REMARKS

In an Official Action dated April 21, 2006, the Examiner withdrew the previous allowance and rejected claims 1, 2, 4-10, 13-30, 32, 54-57, 60-73 and 76-79 as anticipated by U.S. Publication No. 2004/0111063 and rejected claims 11, 12, 31, 58, 59, 74, 75 and 80-89 as obvious over the '063 Application in combination with U.S. Patent No. 5,181,909. Applicants request that the Examiner reconsider the rejection in light of the following discussion.

The '063 Application is directed to a variety of retractable needle injection devices that are used to provide an injection from a cartridge. One characteristic of the devices in the '063 Application is that the devices are configured to use a cartridge or ampoule having some type of plunger or piston that moves relative to the cartridge housing to expel the fluid from the housing. For instance, the Examiner has cited the embodiment in Figs. 5A-6B. In this embodiment, the pre-filled container is a cartridge 304 that is mounted into a housing 314. Initially, a piston 318 is positioned within the rear end of the cartridge 304, as shown in Fig. 5A. The rear end of the cartridge is open so that a plunger can be connected to the piston 318 to drive the piston forward to expel fluid from the cartridge. To expel the fluid from the cartridge, the piston 318 is displaced forwardly to the front of the cartridge as shown in Fig. 5C.

The injector 310 in the '063 Application also includes a spring housing assembly 328 that houses a retractable needle. The assembly includes several fingers 336 that form hooks 338 that surround and engage a block 330 connected to the needle. The rearward surfaces of the fingers form tapered surfaces. The forward end of the piston 318 has a frustoconical surface that cooperates with the tapered surfaces on the fingers. At the end of an injection the frustoconical piston engages the tapered surface of the fingers to wedge the fingers apart, thereby releasing the needle, as shown in Fig. 6B.

In contrast to the injector 310 in the '063 Application, one feature of the devices in the present application is that the devices can operate with a vial or cartridge that typically requires the fluid to be drawn out of the vial rather than "pushed" out of the cartridge by a piston or other seal. For instance, frequently a syringe is used to provide an injection by drawing a dose of medicine out of a vial and into a syringe. The user inserts the syringe needle through a seal that is fixed to the end of the vial. The user then draws a plunger rearwardly to draw the fluid into the syringe.

By way of example, the first embodiment in the present application includes an injector having a barrel 20 and a vial holder 40 that forms a slideable seal within the barrel. The vial holder 40 is configured to receive a vial 70 having a fixed seal and a fixed closed rearward wall. Prior to an injection, the vial holder 40 is displaced forwardly, which forces air from a chamber 48 into the vial 70 to pressurize the vial. After piercing a mid-seal 50, the positive pressure in the vial forces the fluid from the vial into a transfer chamber 60. The fluid is subsequently expelled from the transfer chamber to provide an injection.

In short, the devices in the present application are operable to withdraw the fluid from a vial even if the vial does not include an element that slides within the vial to expel the fluid.

Referring to claim 1, a device is recited that includes a hollow barrel, a vial holder, a needle, and a transfer chamber. The device in the '063 Application cited by the Examiner does not include a vial holder displaceable within the barrel having a socket configured to receive a vial. The Examiner cites element 304 as being a vial holder, but element 304 is a cartridge, not a holder. As shown in Fig. 6A and described in ¶0064, there is a housing 314 for receiving the cartridge 304, but there is no cartridge or vial holder that is displaceable within the housing.

In addition to not teaching a vial holder, the device in the '063 Application does not teach a transfer chamber. As described above, one feature of Applicants' devices is that the devices include a chamber for receiving the fluid from the vial. The fluid is then expelled from the chamber.

The Examiner cited element 338 in the '063 Application as a transfer chamber, however, element 338 is a hook on an end of a finger that releasably retains the needle. There is no chamber in the '063 Application for receiving fluid from the vial. As shown in Fig. 6B, the rearward end of the injection needle projects into the cartridge 304, therefore, there is no need for a chamber for receiving the fluid. The fluid is expelled directly from the cartridge to the needle and into the patient.

Applicants' undersigned attorney is uncertain, but it appears that the Examiner has confused the space between the cartridge 304 and the rearward end of the needle 307 in Fig 6A as being a chamber that is used during operation of the device. The device does not operate in that way.

Fig. 6A shows the device in a position prior to use, in which the cartridge is spaced apart from the needle so that the needle does not pierce the seal on the cartridge. To prepare the device for use, the cartridge is pushed forwardly until the cartridge abuts the forward end of the device and the needle pierces the cartridge seal, as shown in Fig. 6B. In short, there is never a chamber for receiving fluid. The space is simply a gap between the needle and the cartridge prior to use. As soon as the needle pierces the seal, the fluid flows directly from the cartridge to the needle.

Accordingly, as discussed above, the '063 Application teaches neither a vial holder nor a transfer chamber as recited in claim 1. Therefore, Applicants request that the Examiner reconsider the rejection of claim 1. In addition, many of the features in the dependent claims further distinguish the claims from the cited references.

For instance, claim 2 recites a transfer conduit configured to extend between the vial and the transfer chamber for transferring medicine from the vial to the transfer chamber. The Examiner cited element 307 as being a transfer conduit, however, element 307 is simply the rearward pointed tip of the injection needle. The injection needle extends into the cartridge 304 during use, therefore, there is no need for a transfer conduit. For this reason, claim 2 is further distinct from the cited references.

Additionally, dependent claim 6 recites an air-pump chamber disposed within the vial holder, and a piston operable to pump air from the air pump chamber into the vial to pressurize the fluid in the vial. The Examiner cited element 318 as a air pump chamber and element 356 as a piston. However, element 318 is the piston that is displaceable within the cartridge to expel the medicine from the cartridge, and element 356 is a surface of the piston. There is no air chamber in the device cited by the Examiner. The piston 318 is simply displaced forwardly to expel the fluid from the cartridge. Accordingly, Applicants request that the Examiner reconsider the rejection of claim 6.

Dependent claim 7 recites a lock releasably locking the vial holder and the barrel to prevent relative motion between the vial holder and the barrel. The Examiner cites element 305 as being such a lock. However, element 305 in the '063 Application is a groove that receives a sealing ring 302 to hold the membrane 301 on the end of the cartridge. As discussed above, the '063 Application does not incorporate a vial holder; the cartridge 304 is mounted directly into the housing 314. Since there is no vial holder, there is no need for a lock to prevent relative rotation between the vial holder and the barrel as recited in claim 7. Accordingly, Applicants request that the Examiner reconsider the rejection of claim 7.

Referring to claims 8 and 10-14, the claims recite features that relate to

the transfer chamber, and as discussed above, the device in the '063 Application cited by the Examiner does not include a transfer chamber. For instance, claim 8 recites a piston for expelling fluid from the transfer chamber. Since the device in the '063 Application does not include a transfer chamber, there is no piston to expel fluid from the transfer chamber. Similarly, claim 10 recites that the transfer chamber is displaceable relative to the needle. Again since there is no transfer chamber, there is no teaching of a transfer chamber displaceable relative to the needle. Claims 11 and 12 recite features of a valve between the transfer chamber and the vial. The Examiner has cited the '909 Patent as teaching the valve features, however, there is no teaching or suggestion of a transfer chamber in the '909 Patent. Therefore, even assuming arguendo that the '909 Patent teaches features about a valve, there is no teaching of the features of controlling the flow of fluid between a transfer chamber and a vial, because none of the references teach a transfer chamber. Similarly, claims 13 and14 teach features of seals defined in relation to the transfer chamber. Since there is no teaching of a transfer chamber, there is no teaching of such seals. Accordingly, the additional features in claims 8 and 10-14 further distinguish the claims from the cited references.

Additionally, for claim 18 the Examiner did not even cite any reference relative to the features in claim 18. The claim recites a piston operable to pump air into the vial to pressurize the fluid in the vial. The Examiner did not mention these features in his analysis of the claims, and such a combination of features is neither taught nor suggested by the cited references. Accordingly, Applicants request that the Examiner reconsider the rejection of claim 18.

Referring to independent claim 19, a device is recited that includes a vial comprising a container having a fixed rearward wall closing the rearward end of the container and a fixed pierceable wall sealing the forward end. As discussed above, the device in the '063 application is directed to a device having an open rearward end so

that a piston can be forced through the container to expel fluid from the cartridge. Since the '063 Application does not teach or suggest the combination of the features of claim 19, Applicants request that the Examiner reconsider the rejection of claim 19. Further, many of the features in dependent claims 20-30 and 32 are neither taught nor suggested by the cited references. These additional features, many of which are discussed above, further distinguish the claims from the cited art.

Independent claim 54 recites a medical device cooperable with a needle assembly having a retractable injection needle and a pre-filled container of medicinal fluid. Among other elements, claim 54 recites a housing cooperable with the needle assembly and a chamber in the housing for receiving the medicinal fluid from the vial container, wherein the chamber is configured to receive substantially all of the medicinal fluid. As discussed above, the devices in the '063 do not teach or suggest a device having a chamber configured to receive the medicinal fluid. Referring to Fig. 6B of the '063 Application, the rearward tip of the injection needle projects into the cartridge so that the fluid goes directly from the cartridge to the needle; there is no chamber for receiving the fluid, let alone a chamber for receiving substantially all of the fluid from a vial as recited in claim 54. Accordingly, Applicants request that the Examiner reconsider the rejection of claim 54. Further, many of the features in dependent claims 55-60 are neither taught nor suggested by the cited references. These additional features, many of which are discussed above, further distinguish the claims from the cited art.

Claim 61 recites a medical device for injecting medicinal fluid from a vial containing an amount of medicinal fluid. Among other elements, claim 61 recites a transfer chamber for receiving the medicinal fluid from the vial, wherein the transfer chamber is in fluid communication with the needle. As discussed above, in the device cited by the Examiner, the rearward tip of the injection needle projects into the cartridge so that the fluid goes directly from the cartridge to the needle; there is no chamber for

receiving the fluid. Accordingly, Applicants request that the Examiner reconsider the rejection of claim 61. Similarly, many of the features in dependent claims 62-73 and 76-79 are neither taught nor suggested by the cited references. These additional features, many of which are discussed above, further distinguish the claims from the cited art. Therefore, Applicants request that the Examiner reconsider the rejection of claim 61 and dependent claims 62-73 and 76-79.

Referring to independent claim 80, among other elements, claim 80 recites:

a piston within the housing to provide positive fluid pressure within the vial when the vial is positioned in the socket;

a chamber in the housing for receiving the medicinal fluid from the container; and

a seal operable to expel the medicinal fluid from the chamber through the needle;

The '063 Application teaches a piston that is displaceable relative to the cartridge, but there is no teaching of a chamber in the housing for receiving the medicinal fluid nor is there a seal operable to expel the medicinal fluid from the chamber through the needle. As discussed above, the device in the '063 Application has a needle that projects into the cartridge 304 and the fluid is expelled directly from the cartridge through the needle by displacing a piston 318 within the cartridge.

The Examiner also cited U.S. Patent No. 5,181,909 as a secondary reference relative to claim 80. However, there is no teaching or suggestion of a chamber for receiving the medicinal fluid from the container or a seal operable to expel the medicinal fluid from the chamber through the needle. Accordingly, none of the recited references teach the combination of features in claim 80. Therefore, Applicants request that the Examiner reconsider the rejection of claim 80, along with dependent claims 81-89.

In light of the foregoing, Applicant believes that this application is in form for allowance. The Examiner is encouraged to contact Applicant's undersigned attorney if the Examiner believes that issues remain regarding the allowability of this application.

Respectfully submitted,

DANN, DORFMAN, HERRELL & SKILLMAN
A Professional Corporation
Attorneys for Applicant(s)

By_____
Stephen H. Eland
PTO Registration No. 41,010

Telephone: (215) 563-4100
Facsimile: (215) 563-4044

Petition for Extension Under 37 CFR §1.136(a)

Applicant's undersigned Attorney hereby petitions for an extension of time of **TWO** months beyond the time period set in the last office communication. The proper fee is enclosed as identified in the enclosed Fee Transmittal form.

September 21, 2006
Date of Certificate

Stephen H. Eland
PTO Registration No. 41,010